JAN 2 1 2004

K034031

510(k) Summary
for the 10 mL Bak'Snap DuoPro™ Safety Syringe (DuoProSS™)
(per 21CFR807.92)

1. SPONSOR

M.K. Meditech Co., Ltd.
Suite 702, 7th Floor
No. 5, Chingdau E. Rd.
Taipei, 100
Taiwan, ROC

Contact Person: I-Ming Shih
Telephone: 886-3-3166399, extension 883

Date Prepared: December 23, 2003

2. DEVICE NAME

Proprietary Name: 10 mL Bak'Snap DuoProSS™ Retractable Safety Syringe

Common/Usual Name: Hypodermic Syringe (with needle)

Classification Name: Piston syringe
Hypodermic single lumen needle

3. PREDICATE DEVICES

- 5 mL DuoPro™ Safety Syringe (DuoProSS™) (K022806)

4. DEVICE DESCRIPTION

The 10 mL Bak'Snap DuoProSS™ Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe provided with or without needle. The modifications to the cleared product are the addition of a brand name, a change in syringe volume, and a change in a single syringe material.

5. INTENDED USE

The Bak'Snap DuoPro™ Safety Syringe (DuoProSS™) is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe which is intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

M.K. Meditech Co., Ltd., makes a claim of substantial equivalence of the 10 mL Bak'Snap DuoProSS™ Retractable Safety Syringe to the cited predicate device based on similarities in intended use, design, and technological and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce the risk of sharps injuries. Both the 10 mL Bak'Snap DuoProSS™ and predicate device are provided without a needle or with single-lumen hypodermic needles (variety of lengths and gauges).

Both the 10 mL Bak'Snap DuoProSS™ and the predicate device are provided sterile, single-use, and disposable. Both the 10 mL Bak'Snap DuoProSS™ and the predicate device have two-part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. Both the 10 mL Bak'Snap DuoProSS™ and the predicate device require the user to manually retract the needle-plunger into the syringe barrel, break off the plunger rod, and discard the pieces. M.K. Meditech Co., Ltd., believes that the differences between the 10 mL Bak'Snap DuoProSS™ Retractable Safety Syringe and cited predicate device are minor and they raise no new issues of safety or effectiveness.

7. TESTING

Verification and validation testing presented in this premarket notification includes testing to demonstrate conformance to standards, testing according to FDA guidance (comparison with predicate device), and biocompatibility testing per ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

M. K. Meditech Company Limited
C/O Ms. Rosina Robinson, RN
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K034031
Trade/Device Name: M.K. Meditech Co., Ltd., Bak'Snap DuoProSS™
Retractable Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 23, 2003
Received: December 29, 2003

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

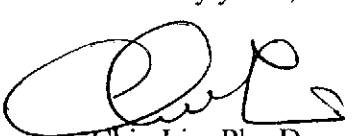
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K034031

510(k) Number (if known):

Device Name: M.K. Meditech Co., Ltd.,
Bak'Snap DuoProSS™ Retractable Safety Syringe

Indications For Use:

The Bak'Snap DuoProSS™ Retractable Safety Syringe is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick Hibbard, Interim Branch Chief

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K034031

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)